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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/889,645	WELCH ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-10,12-16,25,28 and 31-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6-10, 12-16, 25, 28, and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 15, 2008 in response to the Office Action of May 15, 2008 is acknowledged and has been entered. Claims 1, 12, 15 and 31 have been amended. Claims 1, 3, 6-16, 25, 28, 31, and 32 are under examination in this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 1, 3, 6-16, 25, 28, 31, 32 and new claims 33-37 under 35 U.S.C. 103(a) as being unpatentable over Ostreicher et al. (GB 2 045 828 A, 1980) in view of Nebe (WO 96/05846, IDS Paper No. 1) as evidenced by Encyclopedia Britannica (britanica.com/eb/article-9030299/diatomaceous-earth, access 10/5/2006) **is maintained.**

Applicant's arguments have been fully considered but were not found persuasive. Applicants amended the claims to recite that the aqueous liquid is blood plasma. Applicants argue that the starting material in Nebe is the extracted thymus tissue containing cellular debris while the starring material in the present invention is human plasma. In response to Applicant's arguments the Office notes that the limitation of human plasma has been present in claim 12 prior to the amendment of October 15, 2008 and this limitation was discussed as being obvious (see Office action of 5/15/2008). It is acknowledged that Nebe teaches removal of prion from thymus and not plasma as presently claimed. However in view of the teachings of Ostreicher who teaches a method of removal of submicron contaminants such as bacteria and viruses from

biological liquids using a filter comprising a binder, cellulose, diatomaceous earth and perlite particles (see the entire document, particularly claims 1, 2, 8-11, 19, and 20, page 1, lines 20-37, page 2, lines 14-19, and Example V, page 10, lines 47-53), it would have been obvious that human plasma is a biological liquid which can be run on a filter comprising Ostereicher's cellulose, diatomaceous earth and perlite particles. One would have had a reasonable expectation of success to filter human plasma thought Ostereicher's filter because Ostereicher teaches using his filter to filter biological liquids and because Ostreicher's filter removes submicron contaminants. One would have been motivated to use Ostereicher's filter to remove Nebe's prion from human plasma because Ostereicher teaches that his filter can be used to remove submicron contaminants from biological liquids and because Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 to 0.2 microns, as discussed on the record.

Applicants argue that Nebe teaches that three filtration stages are required in order to remove the cellular debris before the resulting liquid can be subjected to the ultrafiltration step. Applicants argue that the present method recites *consisting essentially of* and therefore excludes the multiple stages of Nebe. In response to Applicants arguments the Office notes that the term "consisting essentially of" is construed as "comprising" absent a clear indication in the specification of what the term "consisting essentially of" is intended to encompass (see MPEP 2111.03). It is additionally noted that Ostereicher does not disclose that multiple filtration stages are required when using his filter for filtration of biological liquids. It is noted that the Ostereicher's reference is cited as a primary reference in the present rejection because it teaches the filter of the present invention and the methods of removing submicron contaminants from biological liquids using the filter. Nebe is cited to cure the deficiency of Ostereicher who does

not teach prion proteins and their sizes. Thus it is irrelevant that Nebe teaches multiple filtration stages.

Applicants argue that the submicron contaminants discussed in Ostereicher would not be expected to simulate soluble prion protein in the presence of plasma proteins as provided by the present invention. In response, the Office notes that Applicant failed to provide reasoning to support this statement. It is the position of the Office that prion present in human plasma would be expected to be removed from plasma using Ostereicher's filter because Ostereicher's filter provides retention less than 6 μm and because Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 to 0.2 microns, as discussed on the record.

It is noted that the limitations of new claims 32-37 dependent from claim 31, with regard to the single use filter, filter pretreated with ethanol, and the plasma product comprising immunoglobulins and albumin are recited in claims 1 (now amended to delete the limitation of single use filter), 25 and 28 and were rejected as being obvious as discussed on the record. With regard to the limitation of the aqueous liquid is a cell-free blood plasma product, the skilled artisan knows that the blood plasma is a cell-free liquid. The limitation with regard to the cell-free blood plasma product is considered to be descriptive of blood plasma. Ostereicher teaches filter permeability of 110 l/m2/min (see Tables I-VI and page 11, lines 20-35).

Thus the present invention would have been *prima facie* obvious at the time the invention was made and therefore the rejection is maintained.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648